

Senate Bill No. 842

Passed the Senate August 31, 2002

Secretary of the Senate

Passed the Assembly August 29, 2002

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day of
_____, 2002, at _____ o'clock __M.

Private Secretary of the Governor

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CHAPTER _____

An act to amend Sections 1367.215, 1367.24, 1367.25, 1367.45, 1367.51, and 1374.72 of, and to add Section 1342.7 to, the Health and Safety Code, relating to health care.

LEGISLATIVE COUNSEL'S DIGEST

SB 842, Speier. Health care: prescription drug benefits.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the regulation of health care service plans by the Department of Managed Health Care. Existing law requires health care service plan contracts to provide specified coverage to enrollees and subscribers, including specified benefits regarding prescription drugs. Existing law provides that a violation of the act is a crime.

This bill would specify that certain provisions of the act requiring a health care service plan to include prescription drug benefits shall not be construed to deny or restrict the authority of the Department of Managed Health Care to ensure a plan's compliance with the act when a plan provides coverage for prescription drugs.

The bill would also specify procedures for a plan to request approval from the department for a copayment, deductible, limitation, or exclusion to its prescription drug benefits and would require the department to adopt regulations outlining the standards it uses in reviewing these requests. The bill would require the department to review periodically these regulations and, commencing on or before July 1, 2004, to report annually to the Legislature regarding the implementation of these provisions.

In addition, this bill would provide, subject to specified exceptions, that nonformulary prescription drugs include any drug for which an enrollee's copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug.

The people of the State of California do enact as follows:

SECTION 1. Section 1342.7 is added to the Health and Safety Code, to read:



1342.7. (a) The Legislature finds that in enacting Sections 1367.215, 1367.25, 1367.45, 1367.51, and 1374.72, it did not intend to limit the department's authority to regulate the provision of medically necessary prescription drug benefits by a health care service plan to the extent that the plan provides coverage for those benefits.

(b) (1) Nothing in this chapter shall preclude a plan from filing relevant information with the department pursuant to Section 1352 to seek the approval of a copayment, deductible, limitation, or exclusion to a plan's prescription drug benefits. If the department approves an exclusion to a plan's prescription drug benefits, the exclusion shall not be subject to review through the independent medical review process pursuant to Section 1374.30 on the grounds of medical necessity. The department shall retain its role in assessing whether issues are related to coverage or medical necessity pursuant to paragraph (2) of subdivision (d) of Section 1374.30.

(2) A plan seeking approval of a copayment or deductible may file an amendment pursuant to Section 1352.1. A plan seeking approval of a limitation or exclusion shall file a material modification pursuant to subdivision (b) of Section 1352.

(c) Nothing in this chapter shall prohibit a plan from charging a subscriber or enrollee a copayment or deductible for a prescription drug benefit or from setting forth by contract, a limitation or an exclusion from, coverage of prescription drug benefits, if the copayment, deductible, limitation, or exclusion is reported to, and found unobjectionable by, the director and disclosed to the subscriber or enrollee pursuant to the provisions of Section 1363.

(d) The department in developing standards for the approval of a copayment, deductible, limitation, or exclusion to a plan's prescription drug benefits, shall consider alternative benefit designs, including, but not limited to, the following:

(1) Different out-of-pocket costs for consumers, including copayments and deductibles.

(2) Different limitations, including caps on benefits.

(3) Use of exclusions from coverage of prescription drugs to treat various conditions, including the effect of the exclusions on the plan's ability to provide basic health care services, the amount



of subscriber or enrollee premiums, and the amount of out-of-pocket costs for an enrollee.

(4) Different packages negotiated between purchasers and plans.

(5) Different tiered pharmacy benefits, including the use of generic prescription drugs.

(6) Current and past practices.

(e) The department shall develop a regulation outlining the standards to be used in reviewing a plan's request for approval of its proposed copayment, deductible, limitation, or exclusion on its prescription drug benefits.

(f) Nothing in subdivision (b) or (c) shall permit a plan to limit prescription drug benefits provided in a manner that is inconsistent with Sections 1367.215, 1367.25, 1367.45, 1367.51, and 1374.72.

(g) Nothing in this section shall be construed to require or authorize a plan that contracts with the State Department of Health Services to provide services to Medi-Cal beneficiaries or with the Managed Risk Medical Insurance Board to provide services to enrollees of the Healthy Families Program to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

(h) Nothing in this section shall be construed as prohibiting or otherwise affecting a plan contract that does not cover outpatient prescription drugs except for coverage for limited classes of prescription drugs because they are integral to treatments covered as basic health care services, including, but not limited to, immunosuppressives, in order to allow for transplants of bodily organs.

(i) (1) The department shall periodically review its regulations developed pursuant to this section.

(2) On or before July 1, 2004, and annually thereafter, the department shall report to the Legislature on the ongoing implementation of this section.

(j) This section shall become operative on January 2, 2003, and shall only apply to contracts issued, amended, or renewed on or after that date.

SEC. 2. Section 1367.215 of the Health and Safety Code is amended to read:



1367.215. (a) Every health care service plan contract that covers prescription drug benefits shall provide coverage for appropriately prescribed pain management medications for terminally ill patients when medically necessary. The plan shall approve or deny the request by the provider for authorization of coverage for an enrollee who has been determined to be terminally ill in a timely fashion, appropriate for the nature of the enrollee's condition, not to exceed 72 hours of the plan's receipt of the information requested by the plan to make the decision. If the request is denied or if additional information is required, the plan shall contact the provider within one working day of the determination, with an explanation of the reason for the denial or the need for additional information. The requested treatment shall be deemed authorized as of the expiration of the applicable timeframe. The provider shall contact the plan within one business day of proceeding with the deemed authorized treatment, to do all of the following:

- (1) Confirm that the timeframe has expired.
- (2) Provide enrollee identification.
- (3) Notify the plan of the provider or providers performing the treatment.
- (4) Notify the plan of the facility or location where the treatment was rendered.

(b) This section does not apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration. Coverage for different-use drugs is subject to Section 1367.21.

(c) Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for prescription drugs.

SEC. 3. Section 1367.24 of the Health and Safety Code is amended to read:

1367.24. (a) Every health care service plan that provides prescription drug benefits shall maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. On or before July 1, 1999, every health care service plan that provides prescription drug benefits shall file with the department a



description of its process, including timelines, for responding to authorization requests for nonformulary drugs. Any changes to this process shall be filed with the department pursuant to Section 1352. Each plan shall provide a written description of its most current process, including timelines, to its prescribing providers. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.

(b) Any plan that disapproves a request made pursuant to subdivision (a) by a prescribing provider to obtain authorization for a nonformulary drug shall provide the reasons for the disapproval in a notice provided to the enrollee. The notice shall indicate that the enrollee may file a grievance with the plan if the enrollee objects to the disapproval, including any alternative drug or treatment offered by the plan. The notice shall comply with subdivision (b) of Section 1368.02.

(c) The process described in subdivision (a) by which prescribing providers may obtain authorization for medically necessary nonformulary drugs shall not apply to a nonformulary drug that has been prescribed for an enrollee in conformance with the provisions of Section 1367.22.

(d) The process described in subdivision (a) by which enrollees may obtain medically necessary nonformulary drugs, including specified timelines for responding to prescribing provider authorization requests, shall be described in evidence of coverage and disclosure forms, as required by subdivision (a) of Section 1363, issued on or after July 1, 1999.

(e) Every health care service plan that provides prescription drug benefits shall maintain, as part of its books and records under Section 1381, all of the following information, which shall be made available to the director upon request:

(1) The complete drug formulary or formularies of the plan, if the plan maintains a formulary, including a list of the prescription drugs on the formulary of the plan by major therapeutic category with an indication of whether any drugs are preferred over other drugs.

(2) Records developed by the pharmacy and therapeutic committee of the plan, or by others responsible for developing, modifying, and overseeing formularies, including medical groups,



individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the enrollees of the plan, that fully describe the reasoning behind formulary decisions.

(3) Any plan arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, contracting pharmaceutical benefit management companies, or other entities that are associated with activities of the plan to encourage formulary compliance or otherwise manage prescription drug benefits.

(f) If a plan provides prescription drug benefits, the department shall, as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, review the performance of the plan in providing those benefits, including, but not limited to, a review of the procedures and information maintained pursuant to this section, and describe the performance of the plan as part of its report issued pursuant to Section 1380.

(g) The director shall not publicly disclose any information reviewed pursuant to this section that is determined by the director to be confidential pursuant to state law.

(h) For purposes of this section, “authorization” means approval by the health care service plan to provide payment for the prescription drug.

(i) Nonformulary prescription drugs shall include any drug for which an enrollee’s copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation or in cases in which the drug has been excluded in the plan contract pursuant to Section 1342.7.

(j) Nothing in this section shall be construed to restrict or impair the application of any other provision of this chapter, including, but not limited to, Section 1367, which includes among its requirements that a health care service plan furnish services in a manner providing continuity of care and demonstrate that medical decisions are rendered by qualified medical providers unhindered by fiscal and administrative management.

SEC. 4. Section 1367.25 of the Health and Safety Code is amended to read:

1367.25. (a) Every group health care service plan contract, except for a specialized health care service plan contract, that is



issued, amended, renewed, or delivered on or after January 1, 2000, and every individual health care service plan contract that is amended, renewed, or delivered on or after January 1, 2000, except for a specialized health care service plan contract, shall provide coverage for the following, under general terms and conditions applicable to all benefits:

(1) A health care service plan contract that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration approved prescription contraceptive methods designated by the plan. In the event the patient's participating provider, acting within his or her scope of practice, determines that none of the methods designated by the plan is medically appropriate for the patient's medical or personal history, the plan shall also provide coverage for another federal Food and Drug Administration approved, medically appropriate prescription contraceptive method prescribed by the patient's provider.

(2) Outpatient prescription benefits for an enrollee shall be the same for an enrollee's covered spouse and covered nonspouse dependents.

(b) Notwithstanding any other provision of this section, a religious employer may request a health care service plan contract without coverage for federal Food and Drug Administration approved contraceptive methods that are contrary to the religious employer's religious tenets. If so requested, a health care service plan contract shall be provided without coverage for contraceptive methods.

(1) For purposes of this section, a "religious employer" is an entity for which each of the following is true:

(A) The inculcation of religious values is the purpose of the entity.

(B) The entity primarily employs persons who share the religious tenets of the entity.

(C) The entity serves primarily persons who share the religious tenets of the entity.

(D) The entity is a nonprofit organization as described in Section 6033(a)(2)(A)i or iii, of the Internal Revenue Code of 1986, as amended.

(2) Every religious employer that invokes the exemption provided under this section shall provide written notice to



prospective enrollees prior to enrollment with the plan, listing the contraceptive health care services the employer refuses to cover for religious reasons.

(c) Nothing in this section shall be construed to exclude coverage for prescription contraceptive supplies ordered by a health care provider with prescriptive authority for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for prescription contraception that is necessary to preserve the life or health of an enrollee.

(d) Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for prescription drugs.

(e) Nothing in this section shall be construed to require an individual or group health care service plan to cover experimental or investigational treatments.

SEC. 5. Section 1367.45 of the Health and Safety Code is amended to read:

1367.45. (a) Every individual or group health care service plan contract that is issued, amended, or renewed on or after January 1, 2002, that covers hospital, medical, or surgery expenses shall provide coverage for a vaccine for acquired immune deficiency syndrome (AIDS) that is approved for marketing by the federal Food and Drug Administration and that is recommended by the United States Public Health Service.

(b) This section may not be construed to require a health care service plan to provide coverage for any clinical trials relating to an AIDS vaccine or for any AIDS vaccine that has been approved by the federal Food and Drug Administration in the form of an investigational new drug application.

(c) A health care service plan that contracts directly with an individual provider or provider organization may not delegate the risk adjusted treatment cost of providing services under this section unless the requirements of Section 1375.5 are met.

(d) Nothing in this section is to be construed in any manner to limit or impede a health care service plan's power or responsibility to negotiate the most cost-effective price for vaccine purchases.

(e) Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance



with this chapter when a plan provides coverage for prescription drugs.

SEC. 6. Section 1367.51 of the Health and Safety Code is amended to read:

1367.51. (a) Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2000, and that covers hospital, medical, or surgical expenses shall include coverage for the following equipment and supplies for the management and treatment of insulin-using diabetes, non-insulin-using diabetes, and gestational diabetes as medically necessary, even if the items are available without a prescription:

- (1) Blood glucose monitors and blood glucose testing strips.
- (2) Blood glucose monitors designed to assist the visually impaired.
- (3) Insulin pumps and all related necessary supplies.
- (4) Ketone urine testing strips.
- (5) Lancets and lancet puncture devices.
- (6) Pen delivery systems for the administration of insulin.
- (7) Podiatric devices to prevent or treat diabetes-related complications.
- (8) Insulin syringes.
- (9) Visual aids, excluding eyewear, to assist the visually impaired with proper dosing of insulin.

(b) Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2000, that covers prescription benefits shall include coverage for the following prescription items if the items are determined to be medically necessary:

- (1) Insulin.
- (2) Prescriptive medications for the treatment of diabetes.
- (3) Glucagon.

(c) The copayments and deductibles for the benefits specified in subdivisions (a) and (b) shall not exceed those established for similar benefits within the given plan.

(d) Every plan shall provide coverage for diabetes outpatient self-management training, education, and medical nutrition therapy necessary to enable an enrollee to properly use the equipment, supplies, and medications set forth in subdivisions (a)



and (b), and additional diabetes outpatient self-management training, education, and medical nutrition therapy upon the direction or prescription of those services by the enrollee's participating physician. If a plan delegates outpatient self-management training to contracting providers, the plan shall require contracting providers to ensure that diabetes outpatient self-management training, education, and medical nutrition therapy are provided by appropriately licensed or registered health care professionals.

(e) The diabetes outpatient self-management training, education, and medical nutrition therapy services identified in subdivision (d) shall be provided by appropriately licensed or registered health care professionals as prescribed by a participating health care professional legally authorized to prescribe the service. These benefits shall include, but not be limited to, instruction that will enable diabetic patients and their families to gain an understanding of the diabetic disease process, and the daily management of diabetic therapy, in order to thereby avoid frequent hospitalizations and complications.

(f) The copayments for the benefits specified in subdivision (d) shall not exceed those established for physician office visits by the plan.

(g) Every health care service plan governed by this section shall disclose the benefits covered pursuant to this section in the plan's evidence of coverage and disclosure forms.

(h) A health care service plan may not reduce or eliminate coverage as a result of the requirements of this section.

(i) Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for prescription drugs.

SEC. 7. Section 1374.72 of the Health and Safety Code is amended to read:

1374.72. (a) Every health care service plan contract issued, amended, or renewed on or after July 1, 2000, that provides hospital, medical, or surgical coverage shall provide coverage for the diagnosis and medically necessary treatment of severe mental illnesses of a person of any age, and of serious emotional disturbances of a child, as specified in subdivisions (d) and (e),



under the same terms and conditions applied to other medical conditions as specified in subdivision (c).

(b) These benefits shall include the following:

(1) Outpatient services.

(2) Inpatient hospital services.

(3) Partial hospital services.

(4) Prescription drugs, if the plan contract includes coverage for prescription drugs.

(c) The terms and conditions applied to the benefits required by this section, that shall be applied equally to all benefits under the plan contract, shall include, but not be limited to, the following:

(1) Maximum lifetime benefits.

(2) Copayments.

(3) Individual and family deductibles.

(d) For the purposes of this section, “severe mental illnesses” shall include:

(1) Schizophrenia.

(2) Schizoaffective disorder.

(3) Bipolar disorder (manic-depressive illness).

(4) Major depressive disorders.

(5) Panic disorder.

(6) Obsessive-compulsive disorder.

(7) Pervasive developmental disorder or autism.

(8) Anorexia nervosa.

(9) Bulimia nervosa.

(e) For the purposes of this section, a child suffering from, “serious emotional disturbances of a child” shall be defined as a child who (1) has one or more mental disorders as identified in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders, other than a primary substance use disorder or developmental disorder, that result in behavior inappropriate to the child’s age according to expected developmental norms, and (2) who meets the criteria in paragraph (2) of subdivision (a) of Section 5600.3 of the Welfare and Institutions Code.

(f) This section shall not apply to contracts entered into pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Division 9 of Part 3 of the Welfare and Institutions Code, between the State Department of Health Services and a health care service plan for enrolled Medi-Cal beneficiaries.



(g) (1) For the purpose of compliance with this section, a plan may provide coverage for all or part of the mental health services required by this section through a separate specialized health care service plan or mental health plan, and shall not be required to obtain an additional or specialized license for this purpose.

(2) A plan shall provide the mental health coverage required by this section in its entire service area and in emergency situations as may be required by applicable laws and regulations. For purposes of this section, health care service plan contracts that provide benefits to enrollees through preferred provider contracting arrangements are not precluded from requiring enrollees who reside or work in geographic areas served by specialized health care service plans or mental health plans to secure all or part of their mental health services within those geographic areas served by specialized health care service plans or mental health plans.

(3) Notwithstanding any other provision of law, in the provision of benefits required by this section, a health care service plan may utilize case management, network providers, utilization review techniques, prior authorization, copayments, or other cost sharing.

(h) Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter when a plan provides coverage for prescription drugs.



Approved _____, 2002

Governor

